Tepezza access in Pakistan: the DRAP named-patient pathway

How families and patients in Pakistan obtain Tepezza (teprotumumab) for thyroid eye disease through the Drug Regulatory Authority of Pakistan Personal Use Import framework.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Tepezza is the Amgen (formerly Horizon Therapeutics) brand name for teprotumumab-trbw, a fully human IgG1 monoclonal antibody delivered by intravenous infusion that binds and blocks the insulin-like growth factor 1 receptor (IGF-1R) on orbital fibroblasts, interrupting the autoimmune signaling cascade that drives the inflammation, proptosis, and diplopia of thyroid eye disease. The US FDA approved Tepezza in January 2020 as the first and only therapy indicated for the treatment of Thyroid Eye Disease (TED), also called Graves' orbitopathy. The label was expanded in April 2023 to clarify that the indication covers TED regardless of disease activity or duration. For Pakistani families with moderate-to-severe TED who cannot wait through the symptom-only alternatives of steroids, orbital radiation, and surgical decompression, the DRAP Special Permission for Personal Use Import is the operative pathway for the 24-week course.

Reserved for you.

Why patients in Pakistan reach for Tepezza through NPP

Tepezza is not registered in Pakistan and has no confirmed local stocking as of this module date. The Pakistani families pursuing Tepezza access face a structural reality: Pakistan's TED management protocols still rely predominantly on steroids, orbital radiation, and surgical decompression, none of which target the underlying IGF-1R-driven fibroblast activation. Graves' disease prevalence in Pakistan, combined with under-recognition of moderate-to-severe TED in endocrinology and ophthalmology clinics outside the major tertiary centers, drives a meaningful patient population whose only mechanistic option is international procurement.

Three patterns converge on the Tepezza named-patient route. First, the time-pressured active inflammatory window. TED has a clinical activity window during which intervention has the best evidence base, and watchful waiting through the local steroid-and-radiation cycle can permanently entrench proptosis and diplopia. Families who recognize the active window and have the means to self-fund the international procurement choose to act inside that window. Second, the absence of a registered-and-stocked alternative. Even in the EU (approved June 2025) and the UK (approved May 2025), national reimbursement and hospital formulary access lag the regulatory approval by 12 to 24 months. Pakistan, where the product is not registered at all, faces the same structural gap. Third, the well-defined 24-week course. Unlike chronic biologics, Tepezza is finite: 8 infusions over approximately 21 weeks of dosing, completing a 24-week course of care. For a family willing to commit to a fixed treatment arc, the cost and logistics are bounded and plannable in a way that indefinite chronic therapy is not.

The DRAP Personal Use Import pathway for Tepezza

The Drug Regulatory Authority of Pakistan (DRAP) regulates the import of medicines through its Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, commonly referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES) portal. For Tepezza, because the product is not registered in Pakistan, the application is unambiguously routed through the unregistered-therapeutic-goods sub-pathway, filed institutionally by the dispensing hospital pharmacy or via a DRAP-licensed specialty importer in Karachi or Lahore.

For Tepezza the clinical justification angle is TED-severity-specific and includes mandatory baseline glucose and audiology coordination. A complete application typically includes:

- A clinical justification letter on hospital letterhead from the treating ophthalmologist (orbital subspecialty preferred) or endocrinologist, documenting the FDA-approved on-label indication: adult thyroid eye disease (moderate-to-severe, regardless of disease activity or duration)
- Documentation of TED severity: clinical activity score (CAS), proptosis measurement (Hertel exophthalmometry), diplopia assessment (Gorman score or equivalent), visual function (acuity, color vision, visual fields where indicated), and orbital imaging (CT or MRI) where available
- Documentation of Graves' disease status: thyroid function tests, TSH receptor antibody titres, prior antithyroid therapy or thyroidectomy or radioactive iodine treatment history
- Documentation of prior or considered TED therapy: steroid courses attempted and outcomes, consideration of orbital radiation, consideration of surgical decompression, and the rationale for disease-modifying mechanism-based therapy now
- Mandatory baseline laboratory and audiology workup: baseline fasting glucose and HbA1c (hyperglycemia is a known adverse event in approximately 10 percent of patients in clinical trials, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance), baseline audiometric assessment (hearing impairment including sensorineural hearing loss that may be permanent is reported in approximately 10 percent of patients)
- A recent prescription specifying brand name (Tepezza), generic name (teprotumumab-trbw), 500 mg per single-dose lyophilized vial, patient weight, dosing schedule (10 mg/kg first infusion, then 20 mg/kg every 3 weeks for doses 2 through 8), total vial count for the 24-week course (typically 8 to 12 vials per patient depending on patient weight and institutional waste rules)
- The treating physician's PMDC license verification
- The patient identifier: CNIC for adult patients, passport for foreign nationals; Tepezza is approved only for adults
- Product details: manufacturer Amgen Inc. (Thousand Oaks, California; Tepezza is now under the Amgen rare disease portfolio following the October 2023 acquisition of Horizon Therapeutics), strength, dosage form, quantity, batch number where available
- The destination dispensing facility license, plus an infusion-suite letter confirming infusion capability, trained nursing staff, reconstitution and dilution capability (each vial requires reconstitution with 10 mL Sterile Water for Injection and dilution into a 0.9 percent sodium

chloride infusion bag for IV administration; the prepared bag has a limited room-temperature stability window and must be infused same-day)
- A manufacturer or authorized distributor letter confirming the product is genuine Amgen-manufactured Tepezza with intact DSCSA pedigree
- The chain-of-custody plan from the US source through international shipment, including validated 2 to 8 degree Celsius cold-chain handling with continuous temperature monitoring (the lyophilized vial is not freeze-tolerant and is not shippable at ambient temperature; excursions outside the 2 to 8 degree range trigger quarantine review before release for patient infusion)

Routine personal-use cases for unregistered specialty biologics typically clear in 6 to 12 weeks from a complete submission. Reserve Meds plans the first-infusion start date no sooner than 8 to 14 weeks from intake.

Where Tepezza gets dispensed in Pakistan

Tepezza is a refrigerated biologic that is reconstituted, diluted, and infused over 60 to 90 minutes. The first two infusions are given over 90 minutes; if well tolerated, subsequent infusions may be shortened to 60 minutes per institutional protocol. Each infusion is weight-calculated and prepared per infusion. Dispensing facilities must have validated 2 to 8 degree Celsius storage, an infusion suite with trained nursing staff, reconstitution and dilution capability, and audiometry access on-site or by referral. The natural homes for Tepezza in Pakistan are Aga Khan University Hospital in Karachi, with its tertiary ophthalmology and endocrinology services, infusion-suite capability, and on-site audiology; Shifa International Hospital in Islamabad, with its established import pharmacy workflow; Liaquat National Hospital in Karachi; the Combined Military Hospitals network at CMH Rawalpindi and CMH Lahore, which carry tertiary ophthalmology and infusion capability; and Shaukat Khanum Memorial Cancer Hospital in Lahore where the infusion-pharmacy workflow is well-developed (though oncology-centric, the same infrastructure supports rare-disease infusions when the referring ophthalmologist or endocrinologist is appropriately credentialed).

The 24-week treatment arc requires same-facility continuity across all 8 infusions, which favors a single dispensing facility for the full course. Patients from secondary cities typically travel to a major-city dispensing facility for the 21-week dosing window and arrange accommodation locally if home is more than a few hours away. Smaller hospitals outside Karachi, Lahore, and Islamabad typically partner with a DRAP-licensed specialty importer that handles the OIES filing and chain-of-custody for the multi-vial procurement.

Real cost picture for Tepezza in Pakistan

Reserve Meds quotes Pakistani patients in US dollars and accepts USD wire transfers from any USD-accessible source. The Pakistani Rupee is in the 278 to 280 range against USD in May 2026. Quoting in USD insulates the family from intra-case currency drift across the 24-week arc.

US wholesale acquisition cost for Tepezza is in the range of approximately USD 14,900 to USD 17,500 per 500 mg single-dose vial, with one Amgen list-pricing reference at approximately USD 17,511.13 per vial as of March 2025. A typical 24-week course of 8 infusions consumes 8 to 12 vials depending on patient weight (a 70 kg patient at the maintenance dose of 20 mg/kg uses approximately 2.8 vials per infusion, rounded up to whole vials per institutional waste rules). At list price, a full course is widely cited in the range of approximately USD 138,000 to USD

400,000-plus depending on patient weight and waste assumptions. International 2 to 8 degree Celsius cold-chain logistics from US source to Karachi, Lahore, or Islamabad typically runs USD 800 to USD 2,500 per shipment for the multi-vial procurement, with multiple shipments staged across the 21-week dosing window to align with infusion calendar. On the insurance side, Adamjee Insurance, Jubilee General Insurance and Jubilee Life Insurance, EFU General Insurance, State Life Insurance Corporation, IGI Insurance, and Pak-Qatar Family Takaful each assess named-patient imports case by case, but coverage for unregistered novel biologics at this cost level sits far outside typical formulary. The realistic default is cash-pay, often funded through pooled diaspora remittances. Reserve Meds does not promise a quoted price; firm quotes are issued per patient after patient weight, dispensing facility, and shipping route are confirmed.

Typical timeline for Tepezza in Pakistan

For an established TED patient with documented severity assessment, ophthalmology or endocrinology referral, and baseline glucose and audiology workup complete, the typical end-to-end cycle from intake to first infusion is 8 to 14 weeks. The DRAP NOC step generally runs 6 to 12 weeks for unregistered novel biologics. US-side sourcing through an authorized Amgen distributor with DSCSA-compliant T3 pedigree adds 1 to 2 weeks for the initial procurement; subsequent procurements within the 21-week dosing window run faster. International 2 to 8 degree Celsius cold-chain transit, FBR Customs clearance, and final delivery to the dispensing facility are typically 5 to 8 days per shipment. Reserve Meds coordinates the procurement cadence against the infusion calendar so each shipment lands ahead of the scheduled infusion. The 21-week dosing window (8 infusions every 3 weeks from week 1) typically completes with the patient finishing the course at week 21 and clinical reassessment at week 24. Timelines are typical ranges, not promises.

What your physician needs to provide

The clinical justification letter for Tepezza is the centerpiece of the DRAP package. For this product the letter typically includes:

- The confirmed indication: adult thyroid eye disease (moderate-to-severe), with documentation of CAS, proptosis measurement, diplopia assessment, visual function, and orbital imaging where available
- Documentation of Graves' disease history: thyroid function tests, TSH receptor antibody titres, prior antithyroid therapy or thyroidectomy or radioactive iodine treatment history
- Prior TED therapy attempted: steroid courses, orbital radiation considerations, surgical decompression considerations, and the rationale for disease-modifying mechanism-based therapy
- Mandatory baseline workup: fasting glucose and HbA1c (hyperglycemia is reported in approximately 10 percent of patients, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance, requiring baseline and on-treatment glucose monitoring), baseline audiometric assessment (hearing impairment including sensorineural hearing loss that may be permanent is reported in approximately 10 percent of patients, requiring baseline audiologic assessment and on-treatment monitoring per clinician judgment)
- The dosing plan: 10 mg/kg for the first infusion, 20 mg/kg for infusions 2 through 8, administered intravenously once every 3 weeks, for a total of 8 infusions over

approximately 21 weeks of dosing, completing a 24-week course; doses are weight-calculated and not interchangeable across patients

- The monitoring plan: hyperglycemia surveillance (glucose monitoring during the 24-week course, especially in patients with preexisting diabetes or impaired glucose tolerance), audiometric surveillance (on-treatment audiology per clinician judgment, particularly if the patient reports any hearing change), inflammatory bowel disease flare surveillance, infusion reaction monitoring during and after each infusion, premedication for infusion reactions at the discretion of the treating clinician
- Confirmation that the patient is not pregnant and counseling on pregnancy considerations

The treating physician's PMDC license verification anchors the application. Ophthalmologists (orbital subspecialty preferred), endocrinologists, and internal medicine physicians with thyroid-and-orbital experience at the major tertiary centers all have signing authority on Personal Use Import clinical justification letters.

Common questions about Tepezza in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Tepezza? Coverage for unregistered novel biologics at this cost level is uncommon across Pakistani health plans. Some plans pay a partial percentage on a case-by-case basis for established indications. We supply the documentation the insurer needs to assess the claim; the realistic default is cash-pay, frequently funded through pooled family resources including overseas remittances from relatives in the Gulf, the UK, and North America.

Why are baseline glucose and audiology required before the first infusion? Hyperglycemia and hearing impairment are the two highest-attention monitoring items in the Tepezza label. Approximately 10 percent of patients in clinical trials reported hyperglycemia, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance. Approximately 10 percent reported hearing impairment, including cases of sensorineural hearing loss that may be permanent. Reserve Meds case protocols require both baselines to be in the file before infusion 1 is scheduled. This is the operating standard, not a recommendation.

Is there a competitor or alternative? No FDA-approved disease-modifying alternative exists for TED. Steroids, orbital radiation, and surgical decompression are symptom and structure interventions, not mechanism-of-action therapies. Steroids reduce inflammation but do not address the IGF-1R-driven fibroblast activation that drives proptosis.

Can Tepezza be re-administered if I do not fully respond? Re-treatment has been studied in the OPTIC-X extension trial for patients who did not respond to the initial course or who relapsed. Re-treatment is a clinician-led decision and is outside the routine label regimen. Reserve Meds coordinates the standard 8-infusion course; re-treatment cases are evaluated separately.

What is the safety profile? In the OPTIC Phase 3 trial published in NEJM in 2020, serious adverse events were uncommon. The most frequently reported adverse reactions include muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, and dry skin. Infusion reactions are described and require monitoring during and after each infusion.

What is the typical course duration? Eight infusions over approximately 21 weeks of dosing, completing a 24-week treatment course. There is no maintenance dosing after the 8-infusion course completes.

Where Reserve Meds fits in Tepezza cases

Reserve Meds is a US-based concierge coordinator. We do not replace your ophthalmologist or endocrinologist, do not replace DRAP, and do not replace the dispensing hospital pharmacy or infusion suite. For Tepezza specifically we orchestrate the US-side sourcing through an authorized Amgen distributor with DSCSA-compliant T3 pedigree, prepare the regulatory documentation kit your physician needs for the DRAP Personal Use Import filing through OIES (TED indication letter template, severity documentation, prior-therapy history, mandatory baseline glucose and audiology workup confirmation, weight-based dose calculation, monitoring plan), coordinate the international 2 to 8 degree Celsius cold-chain logistics with continuous temperature monitoring and excursion-management protocols across the multi-shipment procurement, and run a single named coordinator throughout the 24-week arc in English and Urdu. The Tepezza case archetype is a planned 24-week patient relationship with predictable infusion cadence, planned cold-chain procurement against a fixed calendar, and a defined endpoint at infusion 8. Coordinator continuity across the 24-week window is the operating standard.

Next step

If your ophthalmologist or endocrinologist has decided Tepezza is the right next step for your moderate-to-severe TED, and you are within the active inflammatory window where intervention has the best evidence base, the named-patient pathway through DRAP is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician and to the dispensing hospital pharmacy.

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